IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PHILIP MORRIS USA INC.
6601 West Broad Street
Richmond, VA 23230

U.S. SMOKELESS TOBACCO COMPANY LLC
6603 West Broad Street
Richmond, VA 23230

R.J. REYNOLDS TOBACCO COMPANY
401 N. Main Street
Winston-Salem, NC 27101

AMERICAN SNUFF COMPANY, LLC
813 Ridge Lake Boulevard
Memphis, TN 38120

SANTA FE NATURAL TOBACCO COMPANY, INC.
One Plaza La Prensa
Santa Fe, NM 87507

ITG BRANDS LLC
714 Green Valley Road
Greensboro, NC 27408

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION
10903 New Hampshire Avenue
Silver Spring, MD 20993

Civil Action No. 1:15-cv-1590

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
200 Independence Avenue SW
Washington, DC 20201

SYLVIA M. BURWELL, in her official capacity as Secretary of Health and Human Services
Office of the Secretary
200 Independence Avenue SW
Washington, DC 20201

and

STEPHEN OSTROFF, M.D., in his official capacity as Acting Commissioner of the Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Defendants.

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

INTRODUCTION

1. Plaintiffs bring this lawsuit to challenge recent action by the United States Food and Drug Administration ("FDA") seeking to assert a broad power of prior restraint over Plaintiffs' marketing communications, even though the Federal Food, Drug, and Cosmetic Act ("FDCA"), as amended by the Family Smoking Prevention and Tobacco Control Act ("TCA"), Pub. L. No. 111-31, plainly denies FDA that power and the First Amendment bars it. Furthermore, FDA engaged in this unlawful action under the guise of a "guidance" to avoid the notice-and-comment requirements of the Administrative Procedure Act ("APA") and subsequent judicial review, even though this putative "guidance" sets forth FDA's final conclusions and creates specific legal obligations with clear and draconian consequences for violations.

2. In June 2009, Congress enacted the TCA, which conferred on FDA specific regulatory authorities regarding the manufacture, marketing, and sale of tobacco products, including cigarettes and smokeless tobacco products manufactured by Plaintiffs.

3. The TCA differentiates between regulation of a "tobacco product" and regulation of a tobacco product's "label." With respect to a "tobacco product," manufacturers generally must obtain authorization from FDA before making any significant change to cigarettes, smokeless tobacco, or any other FDA-regulated tobacco product on the market. By contrast, with respect to a tobacco product's "label," Congress rejected giving FDA power to pre-approve changes except in two narrow circumstances: (1) where the label makes a "modified risk" claim; and (2) where FDA adopts a specific pre-approval regulation through notice-and-comment rulemaking.

4. On March 4, 2015, FDA issued a document entitled, "Guidance for Industry: Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions" ("First SE Directive") [**Exhibit A**], that disregarded Congress's carefully calibrated statutory framework. The First SE Directive effectively required pre-approval of label changes that would render a tobacco product "distinct"—as defined under FDA's vague standards—from the predecessor version of the product, even though there is no change to the tobacco product itself. Specifically, before making such label changes, the First SE Directive required manufacturers to submit a report to FDA and wait at least 90 days for some products and, for other products, until FDA gave its authorization, *i.e.*, indefinitely. In addition, the First SE Directive required pre-authorization of changes to the quantity of products sold, even though such changes in quantity do not change the products themselves.

5. Plaintiffs challenged the First SE Directive in this Court, and FDA promptly adopted an "Interim Enforcement Policy" stating that it was considering additional comments on the First SE Directive and did not "intend to issue any warning letters or take steps to initiate any judicial or administrative adversarial proceedings" pursuant to the First SE Directive during that review. First SE Directive at 1 n.1 (note added May 2015). Plaintiffs therefore dismissed the case without prejudice.

6. On September 8, 2015, FDA issued a new version of the same document, entitled, "Guidance for Industry: Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Edition 2)" ("Second SE Directive") [**Exhibit B**]. The Second SE Directive did not materially change the requirements imposed in the prior version. The Agency merely added some new arguments to attempt to justify them.

7. The Second SE Directive is the latest of FDA's multiple attempts to impose an unlawful pre-authorization requirement for label and product quantity changes. Each time that Plaintiffs refuted FDA's implausible reading of the TCA, the Agency came up with a new, equally strained justification for the same result. The Second SE Directive fares no better than the prior versions.

8. Because the Second SE Directive is at odds with both the structure and the text of the TCA, and does not reflect reasoned decision-making, it is arbitrary and capricious, an abuse of discretion, not in accordance with law, and in excess of statutory jurisdiction, authority, and limitation. It therefore violates the APA.

9. The Second SE Directive also violates the APA because it was issued without observance of procedures required by law. Because it represents the Agency's final conclusions and imposes new legal obligations, the Second SE Directive is in fact a substantive rule. In

adopting it without notice-and-comment rulemaking, FDA violated the APA, as well as the TCA itself, which at a minimum requires public notice and rulemaking before FDA can seek to impose a prior restraint of tobacco product labels not making a "modified risk" claim.

10. The Second SE Directive also violates the First Amendment's strict limitations on prior restraints as well as its protections for commercial speech and the prohibition against vague speech restrictions. The *de facto* requirement in the Second SE Directive to obtain pre-approval of label changes is a prior restraint on speech, yet it contains none of the safeguards that the First Amendment requires when the Government imposes "the most serious and the least tolerable infringement on First Amendment rights." *Neb. Press Ass'n v. Stuart*, 427 U.S. 539, 559 (1976); *see also Se. Promotions Ltd. v. Conrad*, 420 U.S. 546, 559 (1975) (emphasizing that "a free society prefers to punish the few who abuse rights of speech *after* they break the law [rather] than to throttle them and all others beforehand") (emphasis in original). In addition, the Second SE Directive violates the First and Fifth Amendments because it does not adequately apprise manufacturers of the label changes that will trigger FDA's new regulatory requirements.

11. FDA's unlawful actions already have harmed Plaintiffs and threaten greater harms in the future by restricting Plaintiffs' ability to modify their product labels and quantities without FDA pre-authorization and by chilling and restricting protected speech.

12. This Court should declare the Second SE Directive unlawful, vacate it, and enjoin its implementation and enforcement.

JURISDICTION AND VENUE

13. This Court has subject matter jurisdiction under 28 U.S.C. § 1331 because Plaintiffs' causes of action arise under the laws and Constitution of the United States, including the APA, 5 U.S.C. § 702, the TCA, and the First and Fifth Amendments.

14. Venue is proper in this district under 28 U.S.C. § 1391 because Defendants FDA and the Department of Health and Human Services ("HHS") reside in this judicial district, Defendants Secretary Burwell and Acting Commissioner Ostroff perform their official duties in this judicial district, and a substantial part of the events giving rise to this action occurred in this judicial district.

15. The Second SE Directive is "final agency action" that is the culmination of FDA's decision-making process. It imposes new substantive legal requirements and makes clear that manufacturers must comply with those requirements. In particular, the Second SE Directive effectively requires manufacturers to obtain pre-authorization from FDA before changing the labels of their tobacco products or altering the quantity of a tobacco product in a package, or else risk civil and criminal penalties. The Second SE Directive therefore determines legal rights and obligations of tobacco manufacturers, including Plaintiffs, and has significant legal consequences. In addition, the Second SE Directive chills and restricts protected speech.

16. An actual controversy exists between the parties under 28 U.S.C. § 2201, and this Court has authority to grant declaratory and injunctive relief under 28 U.S.C. §§ 2201, 2202, and 5 U.S.C. §§ 705, 706.

PARTIES

17. Philip Morris USA Inc. ("PM USA") is a Virginia corporation headquartered in Richmond, Virginia. PM USA manufactures cigarette products regulated by FDA.

18. U.S. Smokeless Tobacco Company LLC ("USSTC") is a Virginia limited liability company headquartered in Richmond, Virginia. USSTC manufactures smokeless tobacco products regulated by FDA. Prior to 2014, USSTC was known as U.S. Smokeless Tobacco

Manufacturing Company LLC ("USSTMC"). In 2014, USSTMC was merged with, and renamed, USSTC.

19. Plaintiff R.J. Reynolds Tobacco Co., Inc. ("RJRT") is a wholly-owned subsidiary of Reynolds American, Inc. ("RAI"), a North Carolina corporation. RJRT's headquarters are located in Winston-Salem, North Carolina. RJRT manufactures cigarettes and smokeless tobacco regulated by FDA.

20. Plaintiff Santa Fe Natural Tobacco Company, Inc. ("Santa Fe") is a wholly-owned subsidiary of RAI. Santa Fe is a New Mexico corporation and its headquarters are located in Santa Fe, New Mexico. Santa Fe manufactures cigarettes regulated by FDA.

21. Plaintiff American Snuff Company ("ASC") is a wholly-owned subsidiary of RAI. ASC's headquarters are located in Memphis, Tennessee. ASC manufactures smokeless tobacco regulated by FDA.

22. Plaintiff ITG Brands LLC ("ITGB") is a Texas corporation headquartered in Greensboro, North Carolina. ITGB manufactures cigarette products regulated by FDA.

23. Defendant HHS is an executive department of the United States Government. HHS is headquartered in Washington, DC.

24. Defendant FDA is an administrative agency within HHS and is responsible for tobacco product regulation under the TCA.

25. Defendant Sylvia M. Burwell is Secretary of HHS and sued in her official capacity. The Secretary oversees FDA's activities with respect to the TCA.

26. Defendant Stephen Ostroff, M.D. is Acting Commissioner of FDA and sued in his official capacity. The Acting Commissioner is directly responsible for FDA's administration of the TCA.

BACKGROUND

A. The Tobacco Control Act

27. The TCA includes provisions regulating the "tobacco product" and separate provisions regulating the "label" that appears on the package of the tobacco product.

1. Provisions Regulating the "Tobacco Product"

28. Under the TCA, FDA regulates the manufacture, marketing, and sale of "tobacco products," including "new tobacco products." TCA §§ 901(a), 910(a)(1). While Congress sought to prevent and reduce the use of tobacco products by minors and to ensure that consumers are better informed of the risks of such products, Congress also specifically provided for the continued availability and sale of tobacco products to adults. TCA § 3(6), (7); *see* 21 U.S.C. §§ 387g(d)(3), 387j. The TCA prohibits the Secretary from banning existing tobacco products—*i.e.*, cigarettes, smokeless tobacco products, cigars, pipe tobacco, and roll-your-own tobacco products. 21 U.S.C. § 387g(d)(3). Moreover, the statute "grandfathers" tobacco products that were on the market as of February 15, 2007, and makes clear that those grandfathered products do not require FDA's premarket review to remain on the market. 21 U.S.C. § 387j.

29. The TCA defines a "tobacco product" as "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product." TCA § 101(a)(rr)(1). The TCA defines a "new tobacco product" as:

> (A) any tobacco product . . . that was not commercially marketed in the United States as of February 15, 2007; or
>
> (B) any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007.

Id. § 910(a)(1).

30. A central component of the TCA is the requirement that, before commercially marketing a "new tobacco product," manufacturers must either (1) obtain from FDA a premarket authorization order, or (2) submit a report indicating that the "new tobacco product" is "substantially equivalent" to predicate tobacco products commercially marketed in the United States as of February 15, 2007, or previously found to be substantially equivalent to such a product. *Id.* § 910(a)(2)(A); *accord, e.g.*, FDA webinar, *Common Issues Identified During FDA's Scientific Evaluation of Substantial Equivalence Reports* (Aug. 21, 2012), http://www.fda.gov/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/SubstantialEquivalence/ucm304518.htm#4. Additionally, "tobacco products that are modified by adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive," may be exempted from the substantial equivalence process if FDA makes certain specified determinations. TCA § 905(j)(3); *see also* 21 C.F.R. § 1107.1.

31. To reach the market by the premarket authorization route, a manufacturer must submit a premarket tobacco application with extensive evidentiary support, including reports of investigations regarding the health risks of the new tobacco product; a "full statement of the components, ingredients, additives, and properties, and of the principle or principles of operation, of such tobacco product"; and a "full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of" the product. TCA § 910(b)(1)(A)-(C). No tobacco product has ever been the subject of a premarket authorization order—a fact that demonstrates the critical importance of the substantial equivalence pathway discussed below.

32. To reach the market by the substantial equivalence ("SE") route, a manufacturer must submit a report indicating that the new tobacco product is "substantially equivalent" to

predicate tobacco products. *Id.* § 905(j)(1)(A)(i). A new tobacco product satisfies this standard if it has the "same characteristics" as the predicate products, or, if it has different characteristics, it "does not raise different questions of public health." *Id.* § 910(a)(3)(A)(i)-(ii).

33. A manufacturer can commercially market a "new tobacco product" without a premarket authorization order or substantial equivalence finding, if the manufacturer (1) introduced the new tobacco product after February 15, 2007 and before March 22, 2011, and also (2) submitted an SE report before March 22, 2011. *Id.* § 910(a)(2)(B)(i)-(ii). Such a "provisional" product can remain on the market unless and until FDA finds it is not substantially equivalent. *Id.*

34. Unless a product is grandfathered and the product has not been significantly changed since February 15, 2007, or was on the market before March 22, 2011 (and the manufacturer has filed the appropriate SE report), all tobacco products that are marketed and sold to consumers must be cleared by FDA. FDA treats tobacco products that are marketed without the appropriate FDA clearance as "misbranded" and "adulterated," *id.* §§ 903(a)(6), 902(6)(A); Second SE Directive at 2, exposing the manufacturer to substantial civil and criminal penalties. For example, FDA can seize products it contends are misbranded or adulterated, seek an injunction against marketing those products, seek civil penalties of up to $275,000 per violation or approximately $10.5 million in a single proceeding, with potential enhancements and multipliers, or pursue criminal penalties that could also include substantial fines, imprisonment of individuals, and significant collateral consequences. 21 U.S.C. §§ 331-34; 21 C.F.R. § 17.2.

2. Provisions Regulating the "Label" of Tobacco Products

35. The "label" of tobacco products is addressed in separate provisions of the FDCA and the TCA. A tobacco product "label" is defined as "a display of written, printed, or graphic matter upon the immediate container of any article." 21 U.S.C. § 321(k). In this case, the term

"article" refers to a tobacco product. Therefore, by definition, a change to the label by itself cannot create a "new tobacco product" under TCA § 910(a)(1), because that provision requires a change to the "design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient" of a tobacco product itself in order to create a "new tobacco product."

36. Unlike significant changes to the tobacco product, the TCA generally does not require manufacturers to obtain pre-approval from FDA for label changes. Rather, the TCA directs manufacturers to file reports with FDA every six months reflecting material changes in the labeling of their tobacco products. TCA §§ 905(i)(1)(B), (i)(3)(D). If FDA finds a particular change false, misleading, or otherwise unlawful, FDA has authority to pursue the civil and criminal remedies discussed above, in addition to other regulatory measures, such as warning letters.

37. There are only two specific, narrowly circumscribed conditions under which the TCA requires manufacturers to obtain FDA approval before implementing a label change:

a. First, the TCA requires manufacturers to obtain FDA authorization before claiming in a label that a tobacco product presents a "modified risk." *Id.* § 911(a). To support this pre-approval requirement, Congress made specific findings in the TCA addressing the First Amendment standards applicable to restrictions on commercial speech. Congress found a "compelling governmental interest" in ensuring that statements about such "modified risk tobacco products" are accurate and complete, *id.* § 2(40), and that requiring pre-approval was "[t]he only way to effectively protect the public health from the dangers of unsubstantiated modified risk tobacco products," *id.* § 2(43).

b. Second, the TCA authorizes FDA to require "prior approval" of statements on tobacco product labels, but only for limited purposes and only by regulation, which under the APA requires notice-and-comment rulemaking:

> PRIOR APPROVAL OF LABEL STATEMENTS.—The Secretary may, by regulation, require prior approval of statements made on the label of a tobacco product to ensure that such statements do not violate the misbranding provisions of subsection (a) and that such statements comply with other provisions of the Family Smoking Prevention and Tobacco Control Act (including the amendments made by such Act).

Id. § 903(b).

B. FDA's Multiple Failed Attempts at Prior Restraint of Label and Quantity Changes

38. Over the past four years, FDA has suggested varying interpretations of the TCA that would improperly broaden the Agency's regulatory authority over tobacco product labels and product quantities. Each time, when challenged, FDA devised a new rationale for the same predetermined conclusion that the changes create a "new tobacco product" subject to premarket review under the TCA—a results-oriented approach that is antithetical to proper agency decision-making and inconsistent with the plain language of the TCA.

1. FDA's 2011 "Draft Guidance"

39. First, in September 2011, FDA issued a "draft guidance" entitled, "Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions" ("Draft Guidance") [**Exhibit C**]. In the Draft Guidance, FDA claimed that the TCA required manufacturers to submit to FDA review before changing the label of a tobacco product. That assertion rested on FDA's view that the label of a tobacco product "is considered a 'part' of that product" within the meaning of TCA § 910(a)(1)(B). Draft Guidance at 3. According to FDA, "[a] change to any part of a tobacco product after February 15, 2007 makes that product a 'new tobacco product'" subject to FDA premarket review under the TCA. *Id.* Plaintiffs submitted comments to FDA demonstrating that the TCA's structure and text precluded FDA's interpretation, and that FDA's interpretation violated the First Amendment. *See, e.g.*, Altria

Client Services Comments on Draft Guidance at 4-7 (Nov. 8, 2011) [**Exhibit D**]. Plaintiffs emphasized that the label is not "part" of the product, and that the TCA provides for FDA pre-approval of tobacco product labels in only two narrow circumstances, neither of which the Draft Guidance addressed. *Id.* at 6-7. Plaintiffs also explained that requiring pre-approval of label changes would infringe on Plaintiffs' First Amendment rights. *Id.* at 8-10.

2. The First SE Directive

40. On March 4, 2015, more than three years after the Draft Guidance, FDA issued a final guidance, the "First SE Directive" [**Exhibit A**]. While shifting its rationale, FDA continued to assert the authority to impose a pre-authorization requirement for broad categories of label changes, as well as for changes to the quantity of a tobacco product contained in a package.

a. Label Changes

41. In the First SE Directive, FDA "reconsidered" the statutory basis advanced in the Draft Guidance, and correctly concluded, contrary to its prior view, "that a label is *not* a 'part' of the tobacco product." First SE Directive at 4 (emphasis added).

42. FDA instead offered up another novel, yet equally erroneous, interpretation, based on a different provision of the TCA, that yielded the same result. FDA "conclude[d] . . . that if a product's label is modified in any way that renders the product distinct from the predicate, even if its characteristics remain the same, the modified product is a new product under section 910(a)(1)(A) of the [FDCA] because that product was not commercially marketed in the United States as of February 15, 2007." *Id.*

43. The First SE Directive set forth vague and subjective criteria for determining whether a label change rendered a tobacco product "distinct" and thus a "new tobacco product" requiring FDA pre-approval:

> Whether a product with a label change results in a distinct product *depends on the circumstances*. Some types of changes that might result in a distinct product are changes to logo, identifiable patterns of color, product descriptors, or any combination thereof. One consideration would be whether the label change would lead consumers to believe that the product is different from the predicate. Therefore, when a company changes the label of a tobacco product, *FDA believes it is a new product if consumers are likely to perceive it as "new" by virtue of the different label*.

Id. (emphases added).

44. As an example, the First SE Directive stated that changing the background color of a tobacco product's label from green to red "may result in a distinct product," but changing the background color from white to cream "may not result in a distinct product." *Id*. at 5 (capitalization omitted). The First SE Directive further stated that changing the logo image on a label from a star to a lion "may result in a distinct product," but changing from a larger lion to a smaller lion "may not." *Id.* (capitalization omitted).

45. The First SE Directive created an entirely new regulatory framework to implement what was functionally a new pre-approval requirement for changes to tobacco product labels. Among other requirements, the First SE Directive instructed Plaintiffs and other tobacco product manufacturers to submit a new type of substantial equivalence report when they change only the label of a tobacco product and not the tobacco product itself: "If a product is new because it is distinct, but the product has the same characteristics as the predicate tobacco product, then the manufacturer . . . may opt to submit a 'Same Characteristics SE Report' (e.g., the name or logo of the tobacco product is modified in a way that makes it distinct)." *Id.* at 4.

46. Neither the TCA nor any other statute or regulation mentions or otherwise contemplates a "Same Characteristics SE Report."

b. Product Quantity Changes

47. The First SE Directive also announced FDA's "determin[ation] that the introduction of a product for which the product quantity in the package has changed . . . , even if the per weight composition of additives, ingredients, and other features remains the same, renders it a new product . . . because the characteristics (e.g., amounts of ingredients) have changed." *Id.* at 10 (footnote omitted). According to the First SE Directive, absent a discretionary exception by FDA, the manufacturer could not market this "new tobacco product" unless the Agency approved the product through the premarket authorization or substantial equivalence process.

48. The First SE Directive required another new report for these changes: "[W]e have determined that changes to product quantity (when all other product characteristics remain the same) will require a reduced set of information in order for FDA to determine whether the new product is substantially equivalent within the meaning of section 910(a)(3)." *Id.*

49. The First SE Directive described in detail the information required in this "Product Quantity Change SE Report," including "[s]cientific data demonstrating that the change in product quantity is not likely to alter consumer use behavior of the new product compared to the predicate product." *Id.* at 12.

50. Neither the TCA nor any other statute or regulation mentions or otherwise contemplates a "Product Quantity Change SE Report."

51. RAI Services Company, which is affiliated with Plaintiffs R.J. Reynolds Tobacco Company, American Snuff Company, LLC, and Santa Fe Natural Tobacco Company, Inc., submitted comments to FDA demonstrating that FDA's interpretation contravened the structure and text of the TCA. *See* Docket No. FDA-2011-D-0147, RAI Services Company Comments on

First SE Directive, at 2, 5-13 (Apr. 3, 2015). Moreover, the comments explained that FDA's interpretation runs afoul of the First Amendment. *Id.* at 3, 13-17.

3. Plaintiffs' Prior Lawsuit

52. In April 2015, Plaintiffs sued Defendants in this Court, challenging the First SE Directive on statutory and constitutional grounds. *See* Compl., *Philip Morris USA Inc. et al. v. U.S. Food & Drug Admin. et al.*, No. 15-cv-544-APM (D.D.C. filed Apr. 14, 2015). Plaintiffs' Complaint demonstrated that the First SE Directive contravened both the TCA and the APA, exceeded FDA's authority, and violated the First and Fifth Amendments to the Constitution. The Complaint showed that neither a label change nor a change in product quantity makes a tobacco product "new" and thereby subjects it to the TCA's premarket review requirements, because neither change modifies the "tobacco product" itself. *See* Compl. ¶¶ 55-65. The Complaint further established that the First SE Directive was a substantive rule requiring notice-and-comment rulemaking. *See id.* ¶¶ 66-69. And the Complaint demonstrated that the First SE Directive violated the First Amendment by imposing a prior restraint on manufacturers' commercial speech without adequate safeguards against censorship and arbitrary decision-making by FDA, *see id.* ¶¶ 70-74, and was unconstitutionally vague as to what label changes make a product "distinct" in FDA's view, *see id.* ¶¶ 75-79.

53. Rather than respond to Plaintiffs' Complaint, FDA announced on May 29, 2015 that it would evaluate potential changes to the First SE Directive, and agreed not to enforce the provisions of the First SE Directive in the interim. In light of FDA's announcement, Plaintiffs voluntarily dismissed their Complaint without prejudice on June 2, 2015.

4. FDA's Second SE Directive

54. On September 8, 2015, FDA issued the Second SE Directive [**Exhibit B**]. FDA did not materially change the legal requirements that the First SE Directive imposed regarding

label changes and product quantity changes, but rather advanced additional rationales in an effort to support them. It thus squarely rejected the positions set forth in Plaintiffs' prior Complaint and regulatory comments.

a. Label Changes

55. Under the Second SE Directive, as under the First, a company proposing to modify its product label in a way that renders the product "distinct" from its predecessor must file a Same Characteristics SE Report. Second SE Directive at 5. For provisional products, the company must wait at least 90 days after filing the report before implementing the label change. *Id*. at 14. For non-provisional products, the company must wait indefinitely for FDA's permission to market the product with label changes. *Id*. at 14-15.

56. To determine whether a label change renders a product "distinct" from its predecessor, the Second SE Directive reiterates that FDA "intends to consider whether the label change would lead consumers to believe that the product is different from another tobacco product." *Id*. at 8; *see also id.* ("FDA believes it is a new product if consumers are likely to perceive it as 'new' by virtue of the different label."). To that end, the Second SE Directive offers the same unhelpful label-change examples as the First SE Directive did. *Id.*

57. With regard to the statutory basis for these requirements, FDA repeats its assertion that a product with a label change that renders the product "distinct" is "new" under Section 910(a)(1)(A) because it "was not commercially marketed in the United States as of February 15, 2007." *Id*. at 5. Apparently in response to Plaintiffs' lawsuit challenging the Agency's interpretation of the TCA, however, FDA adds yet another interpretation of the TCA to justify the same preordained result. According to FDA, "the 'same characteristics' prong of the SE criteria describes products whose physical attributes are *identical* to those of the predicate." *Id*. at 6 (emphasis added). Based on this premise, FDA argues that if a "new tobacco product"

can result only from changes to the physical attributes of the product, then the "same characteristics" test, which applies only to such new tobacco products, would be superfluous. Therefore, FDA concludes, "Congress must have contemplated that there would be 'new tobacco products' that were physically identical to predicate products that would be cleared for marketing under the 'same characteristics' prong. Products that carry new names or label modifications that render the product distinct, but otherwise have the same physical attributes as a predicate product, fall into this category." *Id.*

58. In support of the claim that a label change can make a tobacco product "new," the Second SE Directive also cites other provisions of the TCA defining the term "brand" and requiring manufacturers in various contexts to identify products by "brand" or "sub-brand." *Id.* at 6 (citing TCA §§ 900(2), 905(i)(1), (i)(3), 904(a)(1), (a)(3), 904(e), as well as other FDA guidance documents that discuss product "brands").

59. The Second SE Directive, unlike the First, attempts to articulate a purpose for requiring the Same Characteristics SE Reports: they are "intended to provide FDA with information needed to conduct the premarket review" and "help[] FDA keep abreast of products in marketplace so that it can properly evaluate whether products are in compliance with the Act, for example whether they are legally marketed." *Id.* at 9.

60. In the exercise of "discretion," FDA in the Second SE Directive carves out two exceptions to enforcement of this ostensible legal bar against products "marketed without a required marketing authorization order." *Id.* at 13. First, for "provisional" tobacco products—*i.e.*, products on the market for which SE reports were submitted before March 22, 2011—the Second SE Directive states that, unless and until FDA finds the underlying provisional product not to be substantially equivalent, "FDA does not intend to object to the commercial distribution

of a new product, that is distinct from, but has the same characteristics as, a product that is subject to a 'provisional' SE Report," as long as the manufacturer submits a Same Characteristics SE Report and then waits 90 days before implementing the label change. *Id.* at 13-14. Second, a manufacturer that has already changed the label of a grandfathered or provisional product currently on the market can continue marketing the product with label changes, but only if the company submits a Same Characteristics SE Report within 30 days of issuance of the Second SE Directive—*i.e.*, by October 8, 2015. *Id*. at 14.

b. Product Quantity Changes

61. The Second SE Directive, like the First, states that a change in the quantity of product in a package renders a tobacco product "new," even if "the per weight composition of additives, ingredients, and other features remains the same." Second SE Directive at 16. FDA maintains that "altering the quantity in the package is a modification of that product (e.g., a change in the amounts of ingredients, materials, other features) resulting in a new product under section 910(a)(1), thus requiring premarket authorization." *Id.* at 17. FDA therefore imposes the same requirements to file Product Quantity SE Reports as in the First SE Directive.

62. As with label changes, FDA announced a discretionary limitation on enforcement of this requirement, stating its intention not to take enforcement action against a new tobacco product that is marketed without a required marketing authorization order, as long as the manufacturer does not implement the quantity change "until 90 days . . . after FDA's receipt of the complete Product Quantity Change SE Report." *Id.* at 23. For grandfathered or provisional products already on the market with a changed product quantity, the manufacturer could continue marketing the product, with the changed quantity, conditioned on submission of a Product Quantity Change SE Report within 30 days after issuance of the Second SE Directive—i.e., October 8, 2015. *Id.*

VIOLATIONS OF LAW

A. The Second SE Directive Conflicts with the Structure and Text of the TCA and Exceeds FDA's Authority

1. FDA's Position that Changes in the Label Can Render a Tobacco Product "New" Conflicts with the Structure of the TCA

63. The TCA authorizes FDA to require pre-authorization of tobacco product labels in two specific and narrow circumstances: first under TCA § 911 when a manufacturer proposes to claim in the label that the product presents a "modified risk"; and second under § 903 when FDA requires prior approval by regulation. The sweeping regime established in the Second SE Directive for pre-authorization of labels falls within neither of these circumstances. It is not limited to modified risk products under TCA § 911, nor was it issued through notice-and-comment rulemaking, which the APA requires for a regulation promulgated under § 903(b).

64. Instead, FDA lodges this new regime for label changes in the substantial equivalence process, which was intended to deal with significant changes to the tobacco product itself, not to the product's label. FDA thus has upended Congress's carefully calibrated statutory structure. While the TCA addresses the physical characteristics of tobacco products and their labels in different provisions, and subjects them to different regulatory frameworks, the Second SE Directive commingles them in one amorphous process.

65. FDA's assertions that the Second SE Directive "does not require the preapproval of the product's label" and that manufacturers "need not submit any product label" with a Same Characteristics SE Report, *id.* at 13, do not alleviate the conflict with the structure of the TCA. Whether or not manufacturers must submit a copy of the new label with the report, the Second SE Directive effectively requires a description of the label change. That change is the only trigger for the requirement that the manufacturer submit the Same Characteristics SE Report and then wait at least 90 days for provisional products and indefinitely for other products before

implementing the change. No matter how FDA describes the process, prohibiting manufacturers from implementing the label change pending an FDA finding of substantial equivalence is tantamount to requiring pre-approval, which Congress denied FDA authority to do except in narrowly defined circumstances not at issue here.

2. FDA's Position that Changes in the Label Can Render a Tobacco Product "New" Conflicts with the Text of the TCA

66. The Second SE Directive not only conflicts with the structure of the TCA, but also with the plain statutory text. FDA conflates the "tobacco product" and the tobacco product's "label," even though FDA has conceded that the "label" is not part of a "tobacco product." Second SE Directive at 3-4; First SE Directive at 4. Specifically, under the Second SE Directive, a product that is physically identical to a previous product but with a label change can fall within the definition of a "new tobacco product" under TCA § 910(a)(1)(A), which provides that a new tobacco product is "any tobacco product . . . that was not commercially marketed in the United States as of February 15, 2007." Second SE Directive at 3. According to the Second SE Directive, a tobacco product with a label change that makes it "distinct" was not previously marketed and is therefore a "new tobacco product" subject to premarket review under the TCA. *Id.*

67. The words "distinct" and "label" appear nowhere in the definition of "new tobacco product." Whether or not a tobacco product is "new" under the statutory definition depends on whether the "tobacco product" was commercially marketed in the United States in 2007, not how it was commercially marketed. TCA § 910(a)(1)(A). Because, as FDA has conceded, the term "tobacco product" does not include the product's label, First SE Directive at 4, a change in the label cannot change the "tobacco product" or by itself create a new tobacco product. If a manufacturer changes the label of a "tobacco product" that was commercially

marketed in the United States as of February 15, 2007, it is still the same "tobacco product" that was marketed on that date; it simply has a different label. There is, accordingly, no basis in § 910(a)(1)(A) of the TCA for FDA to require pre-authorization of that label change.

68. FDA's position also conflicts with the TCA's provision that a new tobacco product is substantially equivalent to predicate products if the new product has the "same characteristics" as the predicates. TCA § 910(a)(3)(A). In FDA's view, a label change that makes a product "distinct" by itself renders that product new and hence requires substantial equivalence review, even if the product's "characteristics remain the same." Second SE Directive at 3. But if the characteristics remain the same and the only change is the label, the products with the old label and the new label by definition are substantially equivalent. Under FDA's theory, the substantial equivalence process would be a meaningless regulatory exercise because it could have only one possible outcome.

69. FDA makes an erroneous argument in response. FDA points out that a product identical to a predicate product is not subject to the substantial equivalence requirement in the first place because it is not a new tobacco product. Therefore, FDA asks, how can a tobacco product not be identical (and thus be subject to the substantial equivalence requirement) but nonetheless have the "same characteristics" (and thus satisfy the substantial equivalence requirement)? FDA suggests that the only possible answer to this question is that a different label, which would cause a product with the same physical characteristics as a predicate not to be identical to the predicate, triggers substantial equivalence review.

70. This argument ignores the purpose and nature of the "same characteristics" test of substantial equivalence. For example, a product may not be identical to any single predicate product but may have the "same characteristics" as a range of predicate products identified by

the applicant. Such a product would be subject to the substantial equivalence test since it would not be an "identical" product but would have the same characteristics as the identified predicate products. Likewise, a new product and the predicate product may have the same components and same ingredients but the quantity of one or more ingredients may differ slightly. These products are the same for all intents and purposes, even if not identical.

71. Further, if Congress had intended to include label changes as part of the SE process, it knew how to do so, and would have said so expressly, as it did in other provisions of the TCA. The statute provides for an assessment of "same *characteristics*." FDA cannot properly read the statute to include in that assessment something FDA itself concedes is not a characteristic.

72. Other TCA provisions that FDA cites in support of its interpretation likewise do not indicate that a "distinct" label change makes a product "new." FDA relies on the TCA's definition of the term "brand" and on other provisions that require manufacturers to report specific information about products according to their "brands." *See* Second SE Directive at 6-7. But the TCA's definition of "new tobacco product" makes no reference to a product's "brand." Nor does the definition of "new tobacco product" mention a product's label or any concept of "distinctness." The "brand"-related provisions on which FDA relies therefore undermine its position: Congress knew how to require tobacco product reporting by "brand" when it wanted, and Congress did not do so in connection with the premarket authorization and substantial equivalence processes for "new tobacco products."

B. FDA Failed to Engage in Reasoned Decision-Making

73. The Second SE Directive fails to provide a reasoned explanation as to how the bar on implementing label and product quantity changes for 90 days or indefinitely will further the objectives of the TCA.

74. In addition, FDA's adoption of a new interpretation of the TCA each time Plaintiffs challenged the Agency's prior interpretation is not consistent with reasoned decision-making.

75. FDA also failed to consider alternatives to its cumbersome and unconstitutional regulatory approach—for example, a notice requirement for label and product quantity changes that would not delay or bar manufacturers' implementation of those changes. FDA articulated no reason for failing to consider such alternatives. *See, e.g., Chamber of Commerce of U.S. v. SEC*, 412 F.3d 133, 145 (D.C. Cir. 2005) (agencies are required to consider "alternative[s]" that are "neither frivolous nor out of bounds").

76. FDA's lack of reasoned decision-making is further manifested in its failure to provide manufacturers adequate guidance to identify label changes rendering the product sufficiently "distinct" to require a Same Characteristics SE Report. FDA's examples of changes that "*might* result in a distinct product" and its statement that a product is distinct "if consumers are likely to perceive it as 'new' by virtue of the different label," Second SE Directive at 8, highlight how arbitrary and obscure the standard is. And an arbitrary or unclear standard promotes arbitrary and inconsistent enforcement. *See Kolender v. Lawson*, 461 U.S. 352, 357 (1983) (regulation must allow "ordinary people" to "understand what conduct is prohibited" so that it "does not encourage arbitrary and discriminatory enforcement").

C. The Second SE Directive Improperly Imposes Legal Obligations Without the Requisite Notice-and-Comment Rulemaking

77. The APA required FDA to conduct notice-and-comment rulemaking because the Second SE Directive is a substantive rule that directs manufacturers to submit new substantial equivalence reports before changing a product label or the product quantity in a package.

78. Even though it was issued as a "guidance" document, the Second SE Directive sets forth FDA's final positions, establishes legal obligations, and makes them binding by subjecting tobacco product manufacturers to the risk of enormous penalties (including seizure of entire product lines found "adulterated" or "misbranded") and the credible threat of prosecution for non-compliance. FDA has now restated the same conclusions three times, leaving no doubt that the guidance reflects the Agency's final position.

79. The Second SE Directive further promulgates a new regulatory scheme with new pathways to product approval and new reporting requirements with specific filing deadlines. The Second SE Directive emphasizes that manufacturers failing to meet the new requirements would be in violation of the FDCA, with the attendant risk of penalties. *See, e.g.,* Second SE Directive at 2-3 (emphasizing that a new tobacco product that does not satisfy the requirements of the FDCA will be considered adulterated and misbranded). In this respect and others, the Second SE Directive clearly reflects FDA's expectation that manufacturers will immediately conform to its requirements or face potential legal consequences. That many manufacturers felt compelled to meet the First SE Directive's original 30-day deadline for filing Same Characteristics SE Reports and Product Quantity Change SE Reports establishes the coercive force of this threat despite FDA's lack of authority to impose that requirement. The Second SE Directive is therefore a substantive rule disguised as a guidance document.

80. FDA's "Interim Enforcement Policy," adopted in response to Plaintiffs' challenge to the First SE Directive, makes clear that, in FDA's view, it has the authority to take enforcement action based on perceived violations of these directives. First SE Directive at 1 n.1. In particular, FDA stated that, during the interim period, it would not "issue any warning letters or take steps to initiate any judicial or administrative adversarial proceedings for marketing a

new tobacco product without required premarket authorization" when the "new product" was the result of a label or product-quantity change. *Id.* If these directives were truly "nonbinding" "guidance," there would have been no need for FDA to adopt an interim *enforcement* policy.

81. TCA § 903(b) independently mandates that FDA conduct notice-and-comment rulemaking when establishing a pre-approval requirement for labeling changes. Under that section, FDA can seek to require pre-approval of tobacco product labels only by issuing a regulation. Instead of adopting a regulation, FDA issued the Second SE Directive that effectively requires manufacturers to obtain FDA's approval before selling a product with a changed label.

82. The Second SE Directive also raises serious separation of powers concerns because it is regulating core private rights—namely, rights protected by the First Amendment—without Congressional authorization and without following the transparent regulatory notice and comment process that the APA requires.

83. FDA's argument that the Second SE Directive does not require pre-approval elevates form over substance. Whatever FDA says it is doing, the result is that a company with a grandfathered or approved product cannot implement a label change unless and until FDA rules on the Same Characteristics SE Report, and a company with a provisional product must submit such a report and wait at least 90 days before implementing the label change.

D. The Second SE Directive Violates the First Amendment

84. Product labels—which, by definition, are displays of written, printed or graphic matter—and brand names are speech protected by the First Amendment.

1. The Second SE Directive Establishes a Prior Restraint on Speech Without Appropriate Limits or Safeguards

85. The Second SE Directive imposes an impermissible prior restraint on protected speech. Under FDA's view, if a manufacturer makes a label change that renders the product "distinct" from its predicates, the manufacturer cannot market the product without pre-authorization—which requires waiting for 90 days in some cases and for an unlimited time in others. FDA is thus preventing manufacturers from communicating with consumers through the product label, through a system of prior restraint.

86. FDA's prior restraint on speech lacks all of the safeguards the Constitution requires to obviate the dangers of censorship as well as arbitrary and irrational decision-making by FDA.

a. There is no deadline for FDA's substantial equivalence determination and thus no time limit on the prior restraint for communications on labels used with non-provisional products. For provisional products, the prior restraint lasts for at least 90 days.

b. For both provisional and non-provisional products, the Second SE Directive fails to provide the requisite narrow, objective, and definite standards to guide FDA's review.

c. For both types of products, the Second SE Directive does not describe the review FDA will undertake while the prior restraint is in force. Although the only difference between the existing product and the one subject to the Same Characteristics SE Report is the new label, that changed label is not even part of the report FDA is reviewing. It is therefore unclear what FDA intends to do with the new reports. The Second SE Directive does not say, other than that FDA will "determine whether the product is lawfully on the market." Second SE Directive at 9.

d. For both types of products, the Second SE Directive places the burden on manufacturers to demonstrate that speech should be permitted, rather than on FDA to show that speech should be suppressed.

e. For both types of products, the Second SE Directive fails to provide an assurance of a prompt and final judicial determination, and fails to place the burden on FDA to institute judicial proceedings in which the constitutionality of the restraint is adjudicated.

87. FDA offers no justification for this system of prior restraint, which lacks adequate safeguards against censorship and arbitrary decision-making.

2. The Second SE Directive Restricts Commercial Speech and Does Not Satisfy the *Central Hudson* Standard

88. FDA's unauthorized restraint on speech does not advance a substantial, much less a compelling, government interest, is far broader and longer in duration than necessary, and lacks any meaningful procedural or substantive safeguards to cabin FDA's decision-making.

89. Even if FDA were to assert a public-health interest that purportedly is served by the FDA-imposed speech restrictions, the Second SE Directive does not directly and materially advance such an interest. FDA makes no showing that restricting product-label changes—which, by definition, do not change the product that a purchaser actually consumes—directly and materially advance a public-health interest.

90. FDA suggests that the Same Characteristics SE Reports are designed to provide it with notice of label changes, allowing the Agency to keep track of products on the market. But a Same Characteristics SE Report does not merely provide notice. It is an *application* that FDA can accept or reject, and it imposes a prior restraint of unlimited duration for some products and at least 90 days for others.

91. If FDA wants notice of label changes, there are far less restrictive ways to get it than imposing a prior restraint without adequate safeguards. The obvious alternative is to require manufacturers to file a notice whenever they make a label change.

92. FDA's restraint on speech is speaker-based because it applies only to manufacturers of tobacco products. It is content-based because it applies only to specific label changes to tobacco products.

E. The Second SE Directive Is Unconstitutionally Vague

93. The Fifth and First Amendments prohibit vague restrictions on protected speech and thus require FDA to apprise companies of the standards FDA will apply in determining which label changes make a product "distinct" and thus require premarket review. The Second SE Directive does not provide such notice.

94. FDA's list of "[s]ome types of changes to the label that *might* result in a distinct product" provides no clarity to companies facing severe penalties if they guess wrong about "distinctness." Second SE Directive at 7 (emphasis added). In fact, FDA's examples highlight how arbitrary and obscure the standard is.

95. FDA states that it "intends to consider whether the label change would lead consumers to believe that the product is different," and that "it is a new product if consumers are likely to perceive it as 'new' by virtue of the different label." *Id*. at 8. This circular approach—it is new if people think it is new—remains unworkably vague and subjective.

96. FDA points to the separate definition of the word "brand" in the TCA. *Id*. at 6-7. But the statutory provisions at issue here do not use the word "brand" or cross-reference the definition. The definition therefore provides no clarity regarding the types of label changes that, in FDA's view, create "distinct" products.

97. If Plaintiffs guess incorrectly and fail to file a report for a label change that in FDA's view triggered the pre-approval requirement, FDA could treat subsequent sales of the product as illegal. This would subject Plaintiffs to severe penalties, including product seizure, injunctions, civil penalties with potential enhancements multiplying the impact, and criminal sanctions.

98. The Second SE Directive thus injects intolerable uncertainty and risk into Plaintiffs' marketing of their products, which will chill Plaintiffs and other manufacturers from

exercising their First Amendment right to communicate with consumers through product labels. Further, by establishing vague and imprecise standards for FDA to apply in determining which label changes are subject to FDA pre-market review, the Second SE Directive vests FDA with impermissibly standard-less discretion in making decisions that affect Plaintiffs' First Amendment rights.

F. Changes to the Product Quantity Do Not Render a Product "New"

99. The Second SE Directive also requires manufacturers to submit a Product Quantity Change SE Report before changing the quantity of a product in a package. Standing alone, an increase or decrease in the quantity of a product in a particular package does not make that product "new." It therefore does not trigger the TCA's requirement for premarket authorization or substantial equivalence review.

100. Contrary to FDA's assertion, increasing or decreasing the quantity of a product in a package does not change "the characteristics (e.g., amounts of ingredients, materials, other features, etc.)," Second SE Guidance at 16, of that product. It is the same "tobacco product," with identical ingredients used in identical proportions.

101. The Second SE Directive also improperly requires manufacturers to demonstrate that the product quantity change is not likely to alter consumers' use of the product. The TCA explicitly requires manufacturers to submit information regarding the behavioral aspects of tobacco use in certain contexts. But the Act requires no such information in SE reports. That was a deliberate legislative choice, which FDA seeks to override.

102. Here, too, FDA's interpretation of the TCA conflicts with other provisions in the statute. For example, in TCA § 102, Congress expressly authorized distribution of samples of smokeless tobacco under specified conditions, including a maximum package size smaller than standard smokeless tobacco packaging. In specifying this different package size, Congress in no

way suggested that manufacturers distributing samples of existing products in these smaller packages have created "new tobacco products" subject to premarket authorization or substantial equivalence review. Likewise, Congress did not require submission of any behavioral research prior to the distribution of existing products in such packaging.

G. The Second SE Directive Imposes Concrete Injury and Hardship on Plaintiffs

103. Plaintiffs manufacture and market hundreds of tobacco products. Depending on FDA's vague and unstated interpretation of what label changes make a tobacco product "distinct," Same Characteristics SE Reports purportedly would be required for many of them.

104. Plaintiffs, like other consumer product manufacturers, frequently modify the labels of their products to communicate with consumers about their products.

105. Plaintiffs currently have label changes in various stages of development, from those that are ready to be introduced to those anticipated for release in the coming months.

106. Plaintiffs collectively manufacture hundreds of "provisional" tobacco products that currently would be subject to a minimum 90-day ban on label changes. Plaintiffs therefore cannot make any label changes to those products that would render them "distinct" from the product under substantial equivalence review without submitting a Same Characteristics SE Report to FDA and then waiting at least 90 days before introducing the label change.

107. With respect to grandfathered products and those provisional products for which FDA issues a substantial equivalence order, Plaintiffs are prohibited from commercially marketing those tobacco products with "distinct" label changes for an indefinite period of time, until FDA determines that the product with label changes that is the subject of the Same Characteristics SE Report is substantially equivalent.

108. If history is a guide, it could take FDA years to rule on Same Characteristics SE Reports. FDA has been criticized for delays in acting on SE reports. U.S. Gov't Accountability Office, GAO-13-723, *New Tobacco Products: FDA Needs to Set Time Frames for Its Review Process* 22 (2013). Because it has misapplied the statute's substantial equivalence requirement, FDA still has not ruled on thousands of SE reports submitted in 2011.

109. The Second SE Directive also harms Plaintiffs by subjecting them to a pre-authorization requirement and other unauthorized regulatory burdens whenever Plaintiffs change the quantity of tobacco product in a package, even when the TCA and FDA regulations mandate the change.

CLAIMS FOR RELIEF

COUNT I

(Violation of the Administrative Procedure Act: the Second SE Directive is Arbitrary, Capricious, and Not in Accordance With the TCA, and Exceeds FDA's Authority by Requiring FDA Pre-Authorization for Tobacco Product Label Changes)

110. Plaintiffs incorporate the preceding paragraphs as if fully set forth herein.

111. The Second SE Directive is "final agency action for which there is no other adequate remedy." 5 U.S.C. § 704.

112. The APA proscribes agency action that is "arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law." *Id.* § 706(2)(A). The APA further proscribes agency action "in excess of statutory jurisdiction, authority, or limitations." *Id.* § 706(2)(C).

113. The TCA differentiates between the regulation of the "tobacco product," on the one hand, and the tobacco product's "label," on the other hand. The "label" is not part of the "tobacco product." Changing a tobacco product's label therefore does not result in a "new tobacco product" subject to FDA pre-authorization under the TCA. The TCA instead permits

FDA to require pre-authorization of label changes in only two narrow circumstances, neither of which applies here.

114. The Second SE Directive broadly requires the pre-authorization of all label changes that supposedly render a non-provisional tobacco product "distinct" from its predicates because the label change results in a "new tobacco product." For provisional products, the Second SE Directive likewise requires that manufacturers submit a Same Characteristics SE Report and then wait at least 90 days before introducing such a label change.

115. The Second SE Directive is arbitrary, capricious, and contrary to the TCA. It also exceeds FDA's authority under the TCA, because it conflicts with the TCA's structure and text.

116. Plaintiffs have no adequate or available administrative remedy; in the alternative, any effort to obtain an administrative remedy would be futile.

117. Plaintiffs have no adequate remedy at law.

118. The Second SE Directive has imposed harm on Plaintiffs, and also imposes definite impending future harm on Plaintiffs.

119. This Court accordingly should declare that the Second SE Directive is unlawful and set it aside. *See* 5 U.S.C. § 706(2).

COUNT II

(Violation of the Administrative Procedure Act: the Second SE Directive is Arbitrary and Capricious Because FDA Failed to Engage in Reasoned Decision-Making)

120. Plaintiffs incorporate the preceding paragraphs as if fully set forth herein.

121. In issuing the Second SE Directive, FDA failed to provide a reasoned explanation as to how the bar on implementing label or product quantity changes for 90 days or indefinitely will further the objectives of the TCA.

122. FDA failed to consider alternatives to the cumbersome and unconstitutional regulatory approach specified in the Second SE Directive and failed to articulate any reasons for rejecting such alternatives.

123. The lack of reasoned decision-making resulted in a Second SE Directive that is arbitrary and capricious because it provides manufacturers inadequate guidance to identify label changes rendering the product sufficiently distinct to require a Same Characteristics SE Report.

124. Plaintiffs have no adequate or available administrative remedy; in the alternative, any effort to obtain an administrative remedy would be futile.

125. Plaintiffs have no adequate remedy at law.

126. The Second SE Directive has imposed harm on Plaintiffs, and also imposes definite impending future harm on Plaintiffs.

127. This Court accordingly should declare that the Second SE Directive is unlawful and set it aside. *See* 5 U.S.C. § 706(2).

COUNT III

(Violation of Administrative Procedure Act, and Section 903(b) of the TCA: Failure to Comply with Procedures Required by Law; Violation of Separation of Powers)

128. Plaintiffs incorporate the preceding paragraphs as if fully set forth herein.

129. The APA proscribes agency action that is "without observance of procedure required by law." 5 U.S.C. § 706(2)(D); *see id.* § 706(2)(A) ("not in accordance with law").

130. FDA issued the Second SE Directive without observing the procedure required by law.

131. The Second SE Directive sets forth final agency positions, imposes legal obligations, establishes severe consequences for non-compliance, and effects changes in existing

law, and accordingly is a substantive rule that FDA was required to promulgate through notice-and-comment rulemaking under the APA. *See* 5 U.S.C. § 553.

132. The Second SE Directive requires premarket authorization of statements made on the label of a tobacco product. Section 903 of the TCA provides that such requirements can be established only by regulation, which requires notice-and-comment rulemaking under the APA, 5 U.S.C. § 553.

133. The Second SE Directive likewise requires premarket authorization of product quantity changes to a tobacco product.

134. The Second SE Directive regulates tobacco manufacturer's private conduct without appropriate legislative authorization and independently violates basic separation of powers principles.

135. Plaintiffs have no adequate or available administrative remedy; in the alternative, any effort to obtain an administrative remedy would be futile.

136. Plaintiffs have no adequate remedy at law.

137. Because FDA promulgated the Second SE Directive without observing procedures required by law, this Court should vacate it as unlawful.

COUNT IV

(Violation of First Amendment to the U.S. Constitution: the Second SE Directive Impermissibly Restricts Protected Speech)

138. Plaintiffs incorporate the preceding paragraphs as if fully set forth herein.

139. Product labels contain commercial speech protected by the First Amendment.

140. The Second SE Directive prohibits manufacturers from changing the label of a tobacco product without first obtaining FDA's pre-authorization (or, with respect to "provisional" tobacco products, without submitting a Same Characteristics SE Report and then

waiting at least 90 days). This is a violation of Plaintiffs' First Amendment right to communicate with consumers through product labels. The Second SE Directive establishes a prior restraint on speech. Yet it does not directly serve a substantial, much less compelling, government interest, is far broader and longer in duration than necessary, and lacks any meaningful procedural or substantive safeguards to cabin FDA's decision-making authority.

141. Plaintiffs have no adequate or available administrative remedy; in the alternative, any effort to obtain an administrative remedy would be futile.

142. Plaintiffs have no adequate remedy at law.

143. As a result, the Second SE Directive violates the First Amendment to the U.S. Constitution and should be set aside. *See* 5 U.S.C. § 706(2)(B).

COUNT V

(Violation of First and Fifth Amendments to the U.S. Constitution: the Second SE Directive Is Unconstitutionally Vague)

144. Plaintiffs incorporate the preceding paragraphs as if fully set forth herein.

145. The Second SE Directive restricts communications in tobacco product labels "if a product's label is modified in any way that renders the product distinct from the predicate." Second SE Directive at 3, 5. The Second SE Directive does not give manufacturers fair notice of the label changes that may result in a "distinct" product subject to FDA pre-approval. Nor does the Second SE Directive articulate clear standards that prevent arbitrary and discriminatory enforcement by FDA officials applying the Second SE Directive.

146. The uncertainty generated by the Second SE Directive chills Plaintiffs' exercise of their First Amendment right to communicate with consumers through product labels because, if Plaintiffs make a label change without submitting it for FDA pre-approval and FDA thereafter

concludes that the change rendered the product "distinct," they will be subject to significant civil and criminal penalties.

147. Plaintiffs have no adequate or available administrative remedy; in the alternative, any effort to obtain an administrative remedy would be futile.

148. Plaintiffs have no adequate remedy at law.

149. As a result, the Second SE Directive violates the First and Fifth Amendments to the U.S. Constitution and should be set aside. *See* 5 U.S.C. § 706(2)(B).

COUNT VI

(Violation of the Administrative Procedure Act: the Second SE Directive is Arbitrary, Capricious, Not in Accordance With the TCA, and Exceeds FDA's Authority by Requiring FDA Pre-Authorization for Product Quantity Changes)

150. Plaintiffs incorporate the preceding paragraphs as if fully set forth herein.

151. The Second SE Directive is "final agency action for which there is no other adequate remedy." 5 U.S.C. § 704.

152. The APA proscribes agency action that is "arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law." *Id.* § 706(2)(A).

153. The Second SE Directive is arbitrary, capricious, and contrary to the TCA, and also exceeds FDA's authority under the TCA because changing the product quantity in a package does not result in a "new tobacco product" subject to FDA pre-approval under the TCA.

154. Plaintiffs have no adequate or available administrative remedy; in the alternative, any effort to obtain an administrative remedy would be futile.

155. Plaintiffs have no adequate remedy at law.

156. The Second SE Directive has imposed harm on Plaintiffs, and also imposes definite impending future harm on Plaintiffs.

157. This Court accordingly should declare that the Second SE Directive is unlawful and set it aside. *See* 5 U.S.C. § 706(2).

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request that this Court enter judgment in their favor and:

a. Declare that the Second SE Directive is arbitrary, capricious, or otherwise not in accordance with law, and exceeds FDA's authority, in violation of the APA, by requiring companies to seek FDA pre-authorization before making certain changes to tobacco product labels;

b. Declare that the Second SE Directive was issued without notice-and-comment rulemaking, in violation of the APA and the TCA;

c. Declare that the Second SE Directive impermissibly restricts protected speech in violation of the First Amendment to the U.S. Constitution;

d. Declare that the Second SE Directive establishes restrictions on protected speech that are vague, overbroad, and lacking in procedural safeguards, in violation of the First and Fifth Amendments to the U.S. Constitution;

e. Declare that the Second SE Directive is arbitrary, capricious, or otherwise not in accordance with law, and exceeds FDA's authority, in violation of the APA, by requiring companies to seek FDA pre-authorization before changing the quantity of a tobacco product in a package;

f. Vacate and set aside the Second SE Directive;

g. Enter a permanent injunction restraining Defendants from implementing or enforcing the Second SE Directive;

h. Award Plaintiffs their litigation costs and reasonable attorneys' fees; and

i. Order such other relief as the Court may deem just and proper.

Dated: September 30, 2015

Respectfully Submitted,

/s/ Robert N. Weiner

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